

09/250,056



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/250,056 02/12/99 MARKS

EXAMINER
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020350 HM22/0728  
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ART UNIT	PAPER NUMBER
HELMS, L	4

DATE MAILED:  
07/28/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire zero month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37-CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-54 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-54 are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
  - ☐ received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice to Comply with Sequence Requirements
- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION IN THE FOLLOWING PAGES--

Art Unit: 1642

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, 34-44, 53-54, drawn to an antibody that binds c-erbB2 receptor epitope, classified in class 530, subclass 388.22.
  - II. Claims 23-33, drawn to a method of delivering a chimeric molecule, classified in class 424, subclass 133.1.
  - III. Claims 45-52, drawn to nucleic acid encoding an antibody that binds to the epitope bound by F5 or C1, classified in class 536, subclass 23.53.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody product of group I can be used for other materially different processes such as immunopurification of the receptor or raising anti-idiotypic antibodies besides the delivery method of group II. Thus the inventions are patentably distinct.
3. Inventions of Groups I and III represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different

Art Unit: 1642

modes of operation, different functions and different effects. The polynucleic acid of Group III, and the antibody of Group I are structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the antibody is raised by immunization.

Furthermore, the polynucleotide can be used for hybridization screening or protein expression, while the antibody can be used to immunopurify the polypeptide or for diagnostic <sup>or</sup> ~~of~~ treatment purposes. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues.

Thus the inventions I and III are patentably distinct.

4. Inventions of Groups II and III represent separate and distinct method and product. The product of Group III is made by materially different method than that of Group II. The product of Group III is used in materially different methods which have different modes of operation, different functions and different effects than the method of Group II. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions II and III are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Tom Hunter on 22 July 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1642

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### *Sequence Requirements*

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

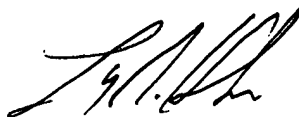
9. APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application

Art Unit: 1642

under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D. whose telephone number is (703) 306-5879.

Larry R. Helms, Ph.D.



July 22, 1999

JULIE BURKE  
PRIMARY EXAMINER

